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STATE OF DELAWARE

OFFICE OF CONTROLLED SUBSTANCES

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PUBLIC MEETING NOTICE: CONTROLLED SUBSTANCE COMMITTEE

DATE AND TIME: Wednesday, October 26, 2016 at 9:00 a.m.

PLACE: Buena Vista Conference Center, Buck Library, First Floor,

661 S. DuPont Highway, New Castle, Delaware 19720

APPROVED: January 25, 2017

MEMBERS PRESENT

Philip Kim, M.D., Medical Representative Art Jankowski, VMD, Veterinary Representative Jo Ann M. Baker, DNP, RN, FNP-C, Nursing Representative Herb E. Von Goerres, R.Ph., Pharmacy Representative Stephen Ruggles, PA-C, PA Representative Mark Hanna, Public Representative

MEMBERS ABSENT

Michael Kremer, DMD, Dental Representative, President Luis Garcia, Jr., DPM, Podiatric Representative, Vice President Alex Zarow, R.Ph., Pharmacy Representative

DIVISION STAFF/DEPUTY ATTORNEY GENERAL

David W. Dryden, R.Ph., J.D., Director, Office of Controlled Substances David Mangler, Director, Division of Professional Regulation Christine Mast, Administrative Specialist III Eileen Kelly, Deputy Attorney General Stacey Stewart, Deputy Attorney General

ALSO PRESENT

Jeanne Chiquoine Tejal Patel MJ Pet

CALL TO ORDER

Mr. Von Goerres called the meeting to order at 9:05 am.

REVIEW AND APPROVAL OF MINUTES

A motion was made by Dr. Jankowski, seconded by Dr. Kim, to approve the minutes for August 24, 2016. The motion unanimously carried.

UNFINISHED BUSINESS

Review of Hearing Officer Recommendations

Ms. Kelly provided a summary of the recommendations for each. She also provided a summary of the disciplinary actions taken by the Board of Medical Licensure and Discipline. The Committee reviewed and deliberated each recommendation and the following motions were placed:

Bruce Grossinger, D.O. – "The Committee declined to adopt the Hearing Officer's recommended discipline, other than the recommended \$3,000 civil penalty. In addition to the civil penalty, the Committee recommends that Dr. Grossinger's CSR shall be suspended for a minimum of six months in that he shall be prohibited during that time period from prescribing or dispensing Schedule II controlled substances. This suspension shall continue until Dr. Grossinger provides the Committee with his office policies and procedures for review and approval. Dr. Grossinger shall be required to submit a written request to lift the suspension of his CSR for review by the Committee and the Secretary. The period of CSR suspension shall be followed by a three year period of probation. During the probationary period, Dr. Grossinger shall undergo quarterly random audits of 10% of his charts with the expense of such auditing to be incurred by Dr. Grossinger.' The recommendation motion was made by Ms. Baker seconded by Mr. Ruggles, with Dr. Kim abstaining. The motion carried.

Steven D. Grossinger, D.O. - "The Committee declined to adopt the Hearing Officer's recommended discipline, other than the recommended \$3,000 civil penalty. In addition to the civil penalty, the Committee recommends that Dr. Grossinger's CSR shall be suspended for a minimum of six months in that he shall be prohibited during that time period from prescribing or dispensing Schedule II controlled substances. This suspension shall continue until Dr. Grossinger provides the Committee with his office policies and procedures for review and approval. Dr. Grossinger shall be required to submit a written request to lift the suspension of his CSR for review by the Committee and the Secretary. The period of CSR suspension shall be followed by a three year period of probation. During the probationary period, Dr. Grossinger shall undergo quarterly random audits of 10% of his charts with the expense of such auditing to be incurred by Dr. Grossinger.' The recommendation motion was made by Ms. Baker seconded by Mr. Ruggles, with Dr. Kim abstaining. The motion carried.

John Brajer, M.D. - "The Committee declined to adopt the Hearing Officer's recommended discipline, other than the recommended \$3,000 civil penalty. In addition to the civil penalty, the Committee recommends that Dr. Brajer's CSR shall be suspended for a minimum of six months in that he shall be prohibited during that time period from prescribing or dispensing Schedule II controlled substances. This suspension shall continue until Dr. Brajer provides the Committee with his office policies and procedures for review and approval. Dr. Brajer shall be required to submit a written request to lift the suspension of his CSR for review by the Committee and the Secretary. The period of CSR suspension shall be followed by a three year period of probation. During the probationary period, Dr. Brajer shall undergo quarterly random audits of 10% of his charts with the expense of such auditing to be incurred by Dr. Brajer.' The recommendation motion was made by Ms. Baker seconded by Mr. Ruggles, with Dr. Kim abstaining. The motion carried.

PRESIDENT'S REPORT

No Report

NEW BUSINESS

DIRECTOR'S REPORT

Case/Diversion Review

Mr. Dryden reported that there have been several robberies over the past six months. They have been inspected and reviewed by Mr. Dryden.

Mr. Dryden has Ms. McCreary has inspected 42 Rite-Aid pharmacies over the past 6 weeks.

There was a statute change involving Optometrists. They are now authorized to prescribe limited amounts of drugs with several limitations on controlled substances. They must have a controlled substance registration to prescribe controlled substances.

Current Events

DEA will cut amount of opioids produced in U.S. by at least 25 percent

The federal government says that beginning next year it will significantly reduce the amount of prescription painkillers that can be manufactured in the United States. The Drug Enforcement Administration, which serves as the gatekeeper for such medicines, announced this week that it will lower aggregate production quotas for nearly all Schedule II prescription opioids by 25 percent or more beginning in 2017. The agency's decision comes in the midst of a national opioid addiction epidemic that has fueled a surge of overdose deaths in Maine and nationwide. The agency said it based the reductions on data collected from several sources, including estimates of legitimate medical need; retail consumption based on prescriptions that were dispensed; manufacturer's data on actual production, sales, inventory, and exports; and product development needs.

<u>State Policies Mandating PDMP Data Review and Pain Clinic Laws Reduced Opioid Prescribing and Overdose Deaths</u>

From 2006 to 2013, state policies aimed at decreasing inappropriate opioid prescribing reduced the amounts of opioids prescribed as well as the rates of prescription opioid overdose deaths, indicates a study published in *Health Affairs*. Based on IMS Health's National Prescription Audit and government mortality data, the study, "Mandatory Provider Review And Pain Clinic Laws Reduce The Amounts Of Opioids Prescribed And Overdose Death Rates," found that combined implementation of mandated provider review of state prescription drug monitoring program (PDMP) data and pain clinic laws decreased the amount of opioids prescribed by 8% and prescription opioid overdose death rates by 12%. The study notes a reduction in heroin overdose death rates was also observed after the implementation of these policies. Launched in 2011, NABP's PMP InterConnect® enhances the benefits of state prescription monitoring programs (PMPs) by allowing authorized users in the United States to access PMP data from across state lines, for a more complete patient record. Participating state PMPs that use this highly secure communications exchange platform (which does not store data) have access to information that can be an effective means of combating drug diversion and drug abuse nationwide. Currently, 43 states have executed memorandums of understanding to be part of PMP InterConnect, 35 PMPs are connected, and 45 states are expected to be connected to or working toward a connection by the end of 2016.

Dangerous Opioid Carfentanil Poses Threat to Public Health and Safety

Carfentanil, a synthetic opioid 10,000 times more potent than morphine, 100 times more potent than fentanyl, and used as a tranquilizer for elephants and other large mammals, has been linked to a significant number of overdose deaths throughout the US. A recent ABC News article warns that carfentanil is also a chemical weapon that has been "banned from the battlefield under the Chemical Weapons Convention," but "Chinese vendors offer to sell carfentanil openly online." Improper handling of carfentanil, along with fentanyl and other fentanyl-related compounds, has deadly consequences, notes Drug Enforcement Administration (DEA). In September 2016, DEA issued a warning to the public and law enforcement about the health and safety risks of carfentanil, which has been surfacing in communities. The ABC News article notes that there have been 19 carfentanil-related deaths in the Detroit, MI area since July 2016.

PMP Review

No Report

Inspection Report

No Report

Review of Proposed Legislative/Regulatory Changes

Mr. Mangler provided a reminder memo providing guidance and deadlines for any legislative changes that may be needed during the upcoming session.

COMMITTEE REPORTS

Medical Examiner's Report

No Report

DEA Report

No report

Substance Abuse Report

No Report

Law Enforcement Report

No Report

Regulatory Committee Report

No Report

Legislative Committee Report

No Report

INSPECTION REPORT

None

Walgreens Safe Medication Disposal Kiosks

Mr. Dryden explained that 6 depositories will be added to some locations to provide the public an avenue to dispose of drugs that are no longer needed. They will provide the Kiosks and use a reversed distributor to properly destroy the medications. Mr. Dryden has reviewed the Kiosks and provided the locations of the requirements of installation.

COMMITTEE CORRESPONDENCE

Epilepsy Foundation Letter Supporting a Schedule Change for "Cannabidol (CBD)"

OTHER BUSINESS BEFORE THE BOARD

2017 Meeting Schedule

Synthetic Opioid U-47700 aka: "PINKY" - Mr. Mangler reported that this is a research chemical produced in mass quantities from China not currently scheduled and that the DEA was starting the process to reschedule as a schedule 1. This is considered a synthetic opioid/designer drug that has caused several deaths in the United States. Secretary Bullock would like to reclassify to a schedule 1 in this state as soon as possible.

PUBLIC COMMENTS

None

NEXT SCHEDULED MEETING

The next regular meeting will be held on January 25, 2017 at 9:00 am at the Buena Vista Conference Center, Buck Library.

<u>ADJOURNMENT</u>

A motion was made by Dr. Kim, seconded by Mr. Hannah, to adjourn the meeting at 10:25 am. The motion carried.

Respectfully submitted,

Christine Mast

Administrative Specialist III

Office of Controlled Substances